

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2010138	(X3) Date Survey Completed 11/12/2020
Name of Provider or Supplier Pinski Dermatology & Cosmetic Surgery	Street Address, City, State 374 Larry Power Drive, Bourbonnais, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5315	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c)</p> <p>The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures manuals; patient testing logs; patients' test reports; and interview with the laboratory director, the laboratory failed to ensure that it referred patients' specimens to CLIA-certified laboratories. Findings: 1. The laboratory policies and procedures manual reads as follows: "All tissue removed during a biopsy or surgical procedure is sent out to a pathology laboratory." The name, and address location of the reference laboratory is documented in the procedure manual. Direct Immunofluorescent (DIF) biopsies are sent to a 2nd reference laboratory. However, the name and address location was not documented. 2. Review of patient testing logs revealed that specimens were sent to a referral laboratory for processing and /or interpretation. 3. Review of 10 patients' biopsy reports revealed 2 of 10 biopsy results were reported by the referral laboratory for the following dates: a. 09/18/18 b. 03/27/19 4. There was no documentation to show that either of the 2 laboratories the laboratory referred its specimens to are CLIA - certified. 5. On November 12, 2020 at 12:00 PM, the laboratory director confirmed the surveyor's findings.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:
Based on review of the Clinical Laboratory Improvement Amendments Application for Certification (CMS 116); Laboratory Personnel Report (FORM CMS-209); laboratory policies and procedures manuals; and interview with the laboratory director, procedures and changes in procedures were not approved, signed, and dated by the current laboratory director. Findings: 1. There was a new laboratory director listed on the CMS 116 collected during the survey of November 12, 2020. 2. The new laboratory director was also listed as "Laboratory Director" on FORM CMS-209. 3. Documentation in the laboratory's policy and procedures manual shows that the procedures were revised November 10, 2020. 4. The new laboratory director did not sign and date the revised policies and procedures manual. 5. On November 12, 2020 at 12:00 PM, the laboratory director confirmed the surveyor's findings.

D5409

PROCEDURE MANUAL
CFR(s): 493.1251(e)

The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures manuals and interview with the laboratory director, the laboratory failed to maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). Findings: 1. The laboratory had 2 procedures manuals. One for Biopsies. The other for Mohs. 2. On November 12, 2020 at 10:00 AM the laboratory director told the surveyor that the Mohs Surgeon quit in June 2020. He stated, "As of June 2020, we are no longer performing Mohs." 3. There was no documentation to show when the laboratory discontinued its Mohs procedures. 4. On November 12, 2020 at 12:00 PM, the laboratory director confirmed the surveyor's findings.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures manuals; laboratory's quality control (QC) records; patients biopsy reports; patients' biopsy slides; and interview with the laboratory director, the laboratory failed to perform and document the quality of staining material it used to stain its biopsy specimens. Findings: 1. The laboratory's policies and procedures read as follows: "All tissue removed during biopsy or surgical procedure is sent out to a pathology laboratory." 2. There were no procedures or programs and services manuals provided to the surveyor for each reference laboratory the laboratory uses. 3. During survey date November 12, 2020 at 11:30 AM, the surveyor selected 10 patients' biopsy test results along with their corresponding slide (s) for the following dates: a. 08/24/18 b. 09/18/18 c. 11/27/18 d. 03/27/19 e. 06/13/19 f. 12/26/19 g. 02/12/20 h. 03/19/20 i. 05/27/20 j. 08/15/20 4. There was no

documentation to show that QC of the stain was performed when each patients' specimens were stained for 10 of 10 patients' specimens (slides) reviewed for the following dates: a. 08/24/18 b. 09/18/18 c. 11/27/18 d. 03/27/19 e. 06/13/19 f. 12/26/19 g. 02/12/20 h. 03/19/20 i. 05/27/20 j. 08/15/20 5. On November 12, 2020 at 12:00 PM, the laboratory director confirmed the surveyor's findings.